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A Proposed Ethical Framework for Vaccine Mandates: Competing Values and the Case of HPV

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Abstract

Debates over vaccine mandates raise intense emotions, as reflected in the current controversy over whether to mandate the vaccine against human papilloma virus (HPV), the virus that can cause cervical cancer. Public health ethics so far has failed to facilitate meaningful dialogue between the opposing sides. When stripped of its emotional charge, the debate can be framed as a contest between competing ethical values. This framework can be conceptualized graphically as a conflict between autonomy on the one hand, which militates against government intrusion, and beneficence, utilitarianism, justice, and nonmaleficence on the other, which may lend support to intervention. When applied to the HPV vaccine, this framework would support a mandate based on utilitarianism, if certain conditions are met and if herd immunity is a realistic objective.

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ABSTRACT. Debates over vaccine mandates raise intense emotions, as reflected in the current controversy over whether to mandate the vaccine against human papilloma virus (HPV), the virus that can cause cervical cancer. Public health ethics so far has failed to facilitate meaningful dialogue between the opposing sides. When stripped of its emotional charge, the debate can be framed as a contest between competing ethical values. This framework can be conceptualized graphically as a conflict between autonomy on the one hand, which militates against government intrusion, and beneficence, utilitarianism, justice, and nonmaleficence on the other, which may lend support to intervention. When applied to the HPV vaccine, this framework would support a mandate based on utilitarianism, if certain conditions are met and if herd immunity is a realistic objective.

Debates over vaccine mandates raise intense emotions. This is especially true when schoolchildren are the subjects. A recent rise in the number of children who avoid routine inoculations through legal exceptions has alarmed public health advocates, even as the list of mandated vaccinations has continued to expand (Omer et al. 2006). Passionate disputes mark much of the public discourse about when is it ethically appropriate to compel children to receive medical interventions.

DEBATE OVER MANDATES

Vaccines are among the crowning achievements of medicine (see Committee on the Evaluation of Vaccine Purchase Financing in the United States 2003). Childhood diseases that once struck terror in the hearts of parents and condemned thousands to lives of pain and suffering, if they even survived, are now almost forgotten by the public at large. It would be safe

to estimate that throughout the course of the twentieth century, millions of lives have been saved and incalculable misery averted. However, these benefits do not reach large populations unless vaccination is widespread, a result that historically has been promoted in the United States through mandatory administration.

All states condition school attendance on compliance with a schedule of vaccinations. Exceptions are available in all cases for medical reasons, such as vaccine allergies, and for religious objections. In some states, exceptions are also permitted for objections based on broader philosophical concerns. Even with these limitations, vaccine mandates engender intense opposition to what some see as heavy-handed government compulsion. In America, where personal autonomy holds a special place among ethical values, many bristle at the thought of implementing medical interventions through government coercion.

The conflict between public health imperatives and personal autonomy promises to arise with new vigor over proposed mandates for the newly approved vaccine against human papilloma virus (HPV), the pathogen that can cause cervical cancer. This virus is transmitted through sexual contact, and it can remain dormant for several years while an unsuspecting victim infects others. If administered before a woman becomes sexually active, the vaccine confers immunity to several forms of the virus and can interrupt further spread. Proposals to mandate its administration to pre-adolescent girls have met concerns not only over individual autonomy and the possibility of yet to be discovered vaccine side effects, but also over possible interference with the sexual attitudes of families.

A vaccine that protects against HPV, Gardasil™ manufactured by Merck, was approved by the Food and Drug Administration in June 2006, and a second one, manufactured by GlaxoSmithKline, Cervarix™, is pending approval. Clinical testing indicates that both are free of major safety risks, although the possibility of long-term hazards cannot be ruled out for any new pharmaceutical product. A key federal policy advisory panel, the Advisory Committee on Immunization Practices of the Department of Health and Human Services, has recommended that the vaccine be administered to all girls at age 11 or 12 (Brown 2006).

The decision to mandate the vaccine as a condition of school attendance, as is presently done for numerous routine immunizations, resides with the states. Following the FDA approval of Gardasil™, proposals to implement such a requirement were considered in 27 states and the District of Columbia (Kaiser Family Foundation 2008). So far, they have been adopted in only two states, Texas and Virginia, and the Texas mandate, which had

been implemented through an executive order of the governor, subsequently was rescinded after fierce political opposition (see Charo 2007). Nevertheless, mandate proposals remain under consideration in several states, where they continue to generate considerable controversy.

To a significant extent, the two sides in debates over mandates talk at cross-purposes. Public health advocates stress direct benefits to those who are vaccinated and indirect protection to whole populations in which disease-causing agents can be eliminated entirely. To them, these results clearly outweigh the risk of possible vaccine side effects that are usually quite rare. Mandate opponents emphasize respect for individual preference, which they believe should determine whether exposure to risks is tolerated, especially when the nature and extent of those risks are subject to dispute.

Public health ethics so far has failed to ground the discussion in a way that permits dialogue between the opposing sides (Colgrove 2006). What is missing is a common vocabulary that facilitates comparison of the two very different sets of concerns. An analytical framework that embodies such a vocabulary could reshape disjointed debates into manageable policy discussions that may lead to consensus on underlying points. At the least, it can lay out competing concerns in an emotionally neutral context that encourages more productive public discourse.

FOUNDATION OF AN ETHICAL FRAMEWORK

When stripped of its emotional charge, the debate over vaccine mandates can be framed as a contest between competing ethical values (see Beauchamp and Childress 2001, pp. 168, 173, 251, 313, for discussion of the application of ethical values in the context of vaccination decisions). Both sides accept all of these values in isolation. Disagreement arises over the primacy of each when they conflict.

In trumpeting autonomy, mandate opponents rely on an ethical pillar of the U.S. Constitution (Amendment XIV) and on the foundation in law and ethics of a right of competent adults to decline even lifesaving medical treatments (*Bartling v. Superior Court*. 1984. 163 Cal.App.3d 186, 209 Cal.Rptr. 220 (Cal. App. 2 Dist.)). In essence, autonomy recognizes the right of individuals to govern their own behavior. To exercise this right, it is necessary to be free from outside influences and limitations, which are the essential elements of liberty, and to have the ability to comprehend the action to be taken, the alternatives, and the consequences, which are the components of agency. Liberty requires, at a minimum, noninterference with personal affairs. Agency requires more complex considerations of an individual's capabilities, particularly in the context of health care, as

it assumes competence to make a decision. Assessing competence can be particularly challenging with regard to adolescents, because of individual variations in developmental maturity.

Government by its nature exercises coercive authority. This is the essence of law enforcement. Such coercion violates the right to autonomy in the interest of promoting a competing value. A government action of this sort can take the form of a restraint on behavior, for example on use of illicit drugs, or of a positive compulsion to engage in a behavior, such as the acceptance of a vaccine. The ethical challenge in these cases is to assess the relative importance of the competing value that is being overridden and of the characteristics and circumstances of those subject to the government action.

In seeking to protect public health, mandate advocates rely on the values of beneficence, utilitarianism, justice, and nonmaleficence. Beneficence is the moral imperative to act for the benefit of others. It is recognized as a positive obligation to act in certain circumstances, for example, to prevent harm, to help persons with disabilities, and to rescue those in danger. Beneficence can be specific to defined categories of individuals, such as children, the disabled, or the poor, or it can be a general obligation toward all others. In the case of medicine, physicians accept an ethical obligation to act with specific beneficence toward patients upon entering the profession. General public health programs, such as universal mandatory vaccination, reflect general beneficence for which the conceptual underpinning is somewhat less straightforward.

The application of beneficence to overrule autonomy in the case of particular individuals represents paternalism. This describes the attitude of a physician who provides or withholds a treatment in contravention of a patient's wishes based on a perception of the patient's underlying best interests. Paternalism reflects an external judgment of the best ultimate outcome for the patient.

Utilitarianism takes the external judgment one step further to consider the best ultimate outcome for society, as a whole. It implements an explicit balancing of relevant factors to determine the optimum result for the greatest number of people regardless of competing individual needs. Utilitarian concerns can be consistent with those of beneficence, but they can also conflict, as when the best interests of some individuals are at odds with those of the majority.

Utilitarianism supports mandating a vaccine to prevent the harm to society that could be caused by the presence of unvaccinated individuals. This is the most prominent and longstanding justification put forth

by mandate proponents. The Supreme Court relied on this principle in upholding a vaccine mandate against smallpox more than 100 years ago, setting a precedent that remains in effect today (*Jacobson v. Massachusetts*. 1905. 197 U.S. 11). Much of the harm to society results from the loss of an effect known as “herd immunity.” Most infectious agents must reside in a sufficient number of susceptible individuals to maintain their presence. Eradication can occur when the proportion of the population that has been vaccinated is sufficiently large to deny the infectious agent such a reservoir of unimmunized hosts. For most diseases, herd immunity is achieved when the proportion of the population vaccinated is in the range of 90 percent. When the proportion of vaccine declinations exceeds this threshold, the infectious agent can lurk in the population to threaten not only those who are unvaccinated but also many who chose the vaccine but whose immune systems generate insufficient levels of antibodies to confer full protection (May and Silverman 2005).

In this situation, a small number of vaccine declinations can have a devastating impact on a community, so the greatest medical benefit for the greatest number of people is achieved by requiring that everyone receive the vaccine. This is true regardless of whether a mandate is in the best interests of every individual or whether it ignores the interest in autonomy. It is an example of government coercion in the service of a competing ethical consideration. It also reflects an implicit hierarchy of public goods in which health takes precedence over rights.

Justice calls for the fair, equitable, and appropriate distribution of scarce goods. It requires a reasoned system of allocating resources based on an underlying principle such as egalitarianism, fair opportunity, or underlying need. Health care is a scarce resource, so justice demands such a system for determining access. Under most analyses, relying solely on individual wealth to purchase access when life and well-being are at stake would not meet the requirements of fairness. Therefore, a program to encourage widespread use of a health care resource, such as a vaccine, whether through a mandate or otherwise, cannot be just if only those with financial means could comply. Justice requires an equitable means of access (see Daniels 1985; 2008; Daniels and Sabin 2002).

Nonmaleficence is the directive against inflicting harm on others. It covers positive actions that hurt others, as well as lack of care that constitutes negligence and the imposition of risks of harm. Beneficence subsumes an obligation to avoid harm, but nonmaleficence carries an independent duty that applies regardless of attempts to create benefits. The principle of nonmaleficence would conflict with a vaccine mandate, if the vaccine

carries medical risks, as many do. Some recipients would suffer harm to their health that would have been avoided but for the mandate.

ETHICAL FRAMEWORK IN GRAPHIC FORM

The issue for public policy, then, is not which value should be respected, but how they should be weighed in relation to one another. A framework that recognizes this balancing could facilitate a less emotional dialogue and focus debates on more clearly defined elements of disagreement, some of which may be amenable to resolution through empirical investigation. Such a framework can be conceptualized graphically, and it is described below.

The interest in autonomy is most compelling when an individual's behavior causes no harm to him- or herself or to others. It declines as actions threaten to cause injury. Refusal of a vaccination causes injury if it leads the actor to contract the disease or if it facilitates spread of the disease to others. In graphic form, this relationship can be represented by a downward sloping line on a graph in which respect for autonomy is measured on the y axis and severity of harm from a disease on the x axis. In this representation, respect for autonomy declines as the risk of harm grows.

The interest in beneficence can be represented with a line that slopes in the opposite direction (Figure 1). When the risk of harm from a disease is low, there is little need to help those who are susceptible. As the risk increases in terms of the severity of the disease, the interest in intervening on their behalf, for example by forcing them to receive a vaccination, rises along with it.

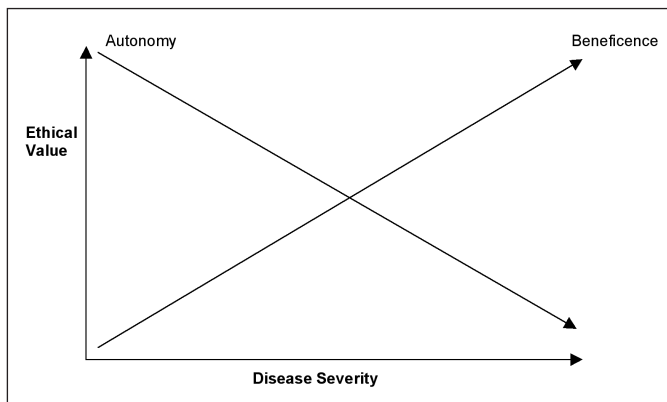


Figure 1. Autonomy vs. Beneficence

A graphic representation of utilitarianism would follow the same trajectory. The imperative to seek the greatest good for a population has little relevance in the face of a minimal risk. It rises with the level of potential harm, which is a function of both the severity of the illness and the contagiousness of the infectious agent.

A line representing justice would be similar. Mandating a vaccine can alleviate disparities in access. It would be difficult to implement or to justify a public policy that conditioned school attendance on vaccination, if availability of the vaccines involved were restricted. Therefore, vaccine mandates trigger several mechanisms that promote universal access. Mandated vaccines are recognized as the medical standard of care, which makes them eligible for private insurance coverage. For those without insurance, public clinics and some schools administer mandated vaccines without charge. Coverage also may be available through the federal Vaccines for Children Program. As the severity of a disease increases, the interest in promoting universal access to a vaccine against it increases as well. This raises the importance of justice as the ethical basis for a mandate both in absolute terms and in relation to the value of autonomy.

A final ethical consideration is nonmaleficence, the directive to avoid harm to others. In the context of a vaccine mandate, such harm would take the form of adverse side effects. As a vaccine reaches higher levels of safety, the confidence with which its use can be coerced without risking harm to patients rises along with it. The concern with protecting autonomy, which in this case embodies the right to decide whether to accept a possible hazard of the vaccine itself, correspondingly declines.

In this graphic scheme, the primary ethical value that militates against vaccine mandates and the primary values that militate in favor move along lines with opposite slopes. At some point, they cross. To the left of this point on the x axis, the disease is mild enough, or contained enough, and the vaccine's safety is uncertain enough, that the interest in autonomy exceeds the imperative to intervene on behalf of individuals or on behalf of the population at large. To the right, the severity or contagiousness of the disease, or the vaccine's safety, elevates the interests in beneficence, utilitarianism, justice, and nonmaleficence above respect for individual choice.

This general representation can be refined by considering the kinds of populations to which a mandate would apply. Three groups that warrant special consideration in this regard are children, health care workers, and members of the military. The interest of each in autonomy falls below that of members of the general public, although their positions relative to one another may be somewhat less clear.

The autonomy of children, from the perspective of ethics and law, is given less weight than that of adults, because they are not considered to have the same decision-making capability. As a legal matter, parents or guardians serve as children's representatives regarding medical decisions, such as acceptance of a vaccine. Mandates aimed at children limit the discretion of parents and guardians in this role. Such restrictions may grant less respect to autonomy when the ultimate object is to protect the children for whom adults care rather than the adults themselves. Adolescents under the age of 18, the target population for HPV mandate proposals, are considered children under the law. Their decision-making capacity clearly differs from that of younger children, but it is not at the same level as adults. Since parental judgment can take account of the preferences of this group, the case to overrule parents' wishes with government mandates is less compelling than when younger children are involved.

Health care workers, it can be argued, voluntarily accept certain medical risks in choosing their occupation and thereby consent to restrictions on their autonomy in this regard. Possible hazards of a vaccination that is required to prevent the spread of a disease to patients are among these risks. Members of the military sacrifice significant amounts of autonomy as an integral part of their service. Among the elements of autonomy that they lose is the freedom to avoid the risk of personal harm when ordered to face a threat. This impairment of autonomy limits the ability to decline medical interventions that are ordered through the chain of command, such as vaccination. In graphic representation, at any level of threat, respect for autonomy is lower for these groups, so the line representing this value moves to the left (Figure 2).

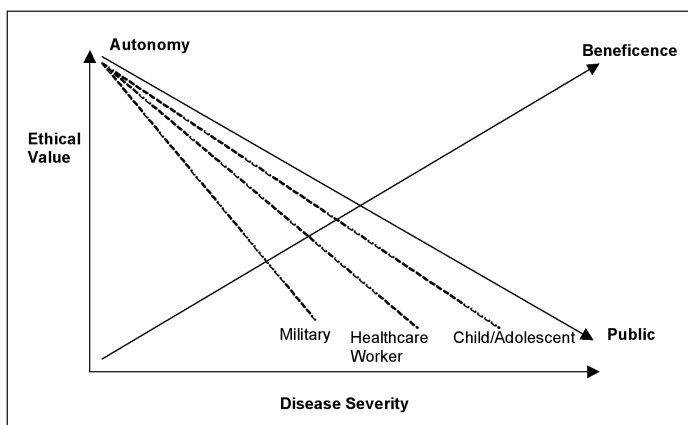


Figure 2. Autonomy of Selected Subgroups

With regard to beneficence, the three groups follow different trajectories. Because they are less able to care for themselves than are adults, ethics recognizes a greater need to oversee the well-being of children. However, less beneficence is called for concerning health care workers and members of the military for similar reasons to those regarding their autonomy. In both cases, their occupations involve the acceptance of risks of harm in the interest of protecting the broader public. The importance of utilitarianism as it affects the spread of a contagious disease is greater for all of the groups. Children are important vectors for many diseases, such as influenza, for both pediatric and adult populations. Health care workers can spread infectious agents to patients, and their ability to continue to work is crucial in the event of an epidemic. Depending on the circumstances, maintaining the health of members of the military may be essential to national defense. With regard to nonmaleficence, more caution is appropriate concerning steps that might harm the health of children than of adults, because of their greater level of helplessness and less developed capabilities for decision making. Less caution is called for regarding risks that might be faced by health care workers and members of the military.

When this set of contests between competing ethical values is synthesized into a single graph, the interest in autonomy can be seen to intersect each of the others at a different point (Figure 3). This produces varying intercepts with the x axis, meaning that the amount of risk that would justify mandating a vaccine, either in terms of disease severity, contagiousness, or vaccine safety, differs in each case. The relative positions of the lines

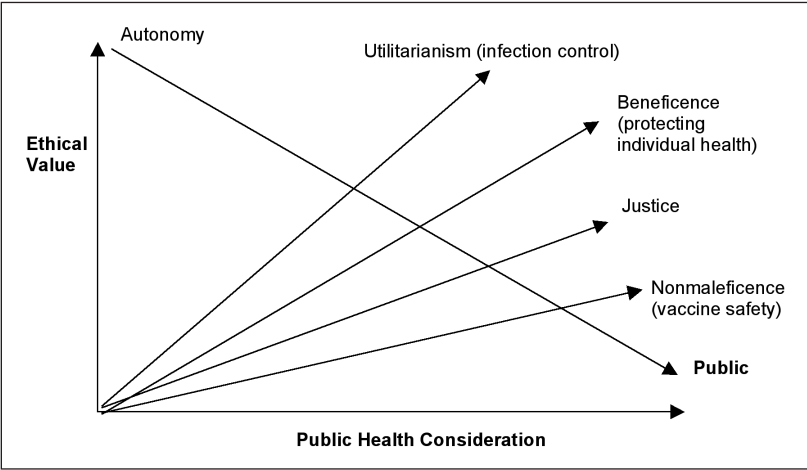


Figure 3. Competing Ethical Concerns in Combination

for a population and for subgroups within it can be assessed based on relevant medical and epidemiological information.

The implication for policy debates is that they can be structured according to the most salient underlying ethical concerns. In a systematic fashion, the graphic framework considers the target population for a vaccine mandate, key characteristics of the disease, its causative agent, the nature of the vaccine, and, perhaps most importantly, the underlying ethical value or values at work. The interplay of these factors tracks their relative importance to each observer, and it isolates the central points of disagreement. Policy debates may then produce more analytical, informed, and inclusive discourse.

THE CASE OF HPV VACCINE

The call to mandate the HPV vaccine offers an opportunity to apply the graphic framework in a practical context. Cervical cancer is a serious and often fatal disease that produced an estimated 9,710 new cases and 3,700 deaths in the United States in 2006 (American Cancer Society 2006). Incidence and mortality are much higher in the developing world. The annual treatment cost in the United States is approximately \$1.7 billion (Brown et al. 2002). However, early detection through Pap smear screening can reduce the mortality rate considerably, a factor that is partially responsible for a drop of almost 50 percent in the death rate between 1982 and 2002 (National Cancer Institute 2006). The disease is contagious but only through sexual relations. Casual contact is not sufficient. Males as well as females can carry and transmit HPV, although a consequent clinical pathology in males has not been definitively identified.

Autonomy concerns regarding HPV vaccination are particularly complex. In addition to apprehension over possible side effects, some mandate opponents contend that offering protection against a sexually transmitted disease implies permission for, or at least acquiescence in, the behavior. At the least, it may interfere with family prerogatives concerning when and how to discuss sexual issues with children. Moreover, unlike diseases such as polio to which there is almost no defense in the face of a contagious patient, HPV transmission can be interrupted behaviorally through abstinence, and even if it is transmitted, the risk to health can be controlled through regular screening.

The graphic framework balances the four ethical values that compete with the autonomy of schoolgirls and their families to make decisions regarding administration of the vaccine. Beneficence is compelled by the

potential severity of cervical cancer, but the case for its application to HPV is limited by the availability of alternative control techniques. The issue that it raises for policy is whether the incremental value of a mandate in preventing disease is substantially greater than that of less coercive measures that promote risk reducing behaviors and vaccination on a voluntary basis. Considerations of justice apply, because the vaccine's cost, more than \$300 for a course of three required doses, could limit access for those who are poor and uninsured. Nonmaleficence in relation to the HPV vaccine is respected when vaccine safety can be assured, which is not yet possible in terms of long-term effects. This value militates in favor of waiting to impose a mandate, perhaps by applying the two-years recommended by the Institute of Medicine before accepting a new drug as safe. (The recommendation is contained in Committee on the Assessment of the U.S. Drug Safety System (2006).)

The most compelling ethical consideration that competes with autonomy in evaluating an HPV vaccine mandate is utilitarianism, in particular, the interest in controlling disease spread. Could a mandate, as opposed to the simple availability of the vaccine, significantly reduce the overall incidence of cervical cancer and the consequent burden to society in morbidity, mortality, and financial costs? The answer to this question requires behavioral observations, epidemiological data, assessment of vaccine efficacy, and projections of vaccine costs. At one extreme, a small marginal effect produced by a mandate would position the interest in utilitarianism below that of autonomy, in other words toward the left-hand end of the x axis. At the other extreme, substantial medical and financial benefits could reverse this order and move the point of intersection to the right on the x axis. This would be the case if the benefits were comparable to those obtained by mandating vaccination against a devastating and highly contagious disease such as polio or, on a speculative basis, avian flu (see Offit 2005, pp. 4–18, for a discussion of polio).

Undoubtedly, the two sides in the debate would differ in their assessment of where the lines representing autonomy and utilitarianism actually cross. What level of societal benefit could outweigh America's cherished respect for individual autonomy and freedom from government coercion? This is a question of individual values that is not amenable to empirical resolution. What the graphic framework contributes is to focus the debate by highlighting the underlying causes of disagreement when all competing concerns are considered together.

A FINAL REFINEMENT TO THE MODEL: HERD IMMUNITY

The ultimate utilitarian benefit from vaccine mandates is to reach the threshold percentage of vaccinated individuals necessary to achieve herd immunity. The implication of this effect for the graphic framework is that the trajectory of utilitarianism is not a straight line. At the point where the threshold for herd immunity is jeopardized, the community interest in coercing widespread vaccination rises precipitously. This increases the slope of the line, moving the point of intersection with autonomy to the left along the x axis (Figure 4). The result is that a lower level of disease severity would ethically justify a vaccine mandate because of the added benefit of herd immunity.

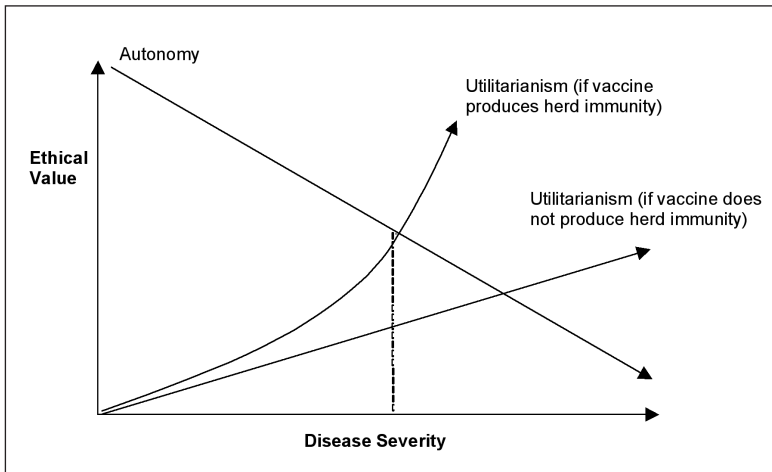


Figure 4. Utilitarianism and Herd Immunity

Herd immunity adds an important consideration to the analysis of the HPV vaccine. If it represents a realistic goal, then the case for making vaccination mandatory becomes considerably more compelling. The potential to achieve herd immunity heightens the conflict between individual preferences and community interests, since the act of declining a vaccine could threaten the health of a large segment of the population, including some women who have been vaccinated (Fine and Clarkson 1986). The relative positions of the relevant ethical values change accordingly.

CONCLUSION

The ethical analysis of vaccine mandates requires a delicate balance of cherished values. Americans prize their autonomy, but contrary communitarian considerations at times intrude. In a legal context, the preamble to the United States Constitution recognizes that liberty may not be denied without due process of the law (United States Constitution, Amendment XIV), yet the Supreme Court recognized more than 100 years ago that individuals may be subject to manifold restraints such as vaccine mandates for the “common good” (*Jacobson v. Massachusetts* 1905. 197 U.S. 11). Public health ethics has just begun to struggle with the conflict between individual autonomy and vaccine mandates. The level of emotion involved may make the debate seem overwhelming, however a structured analytical model could make the clash of values more manageable. This is the contribution of a graphic framework that lays out significant competing concerns simultaneously.

The proposed framework could be refined further to account for additional factors, for example a cost-benefit analysis that might affect utilitarian considerations. Even with refinements, discourse over sensitive issues of values will never be made entirely devoid of emotional charge. Nevertheless, by isolating the central considerations and displaying their interplay, this framework can facilitate more productive public discussion. With a vaccine for HPV under current debate and active research underway for new ones to address scourges such as HIV and avian flu, the same conflicts promise to arise repeatedly for some time to come. Reasoned discourse concerning them is a prerequisite for the formulation of effective public health policy.

This work was developed in conjunction with the Center for Vaccines Ethics and Policy, a program of the Center for Bioethics at the University of Pennsylvania, The Wistar Institute Vaccine Center, and the Vaccine Education Center of Children’s Hospital of Philadelphia.

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